K033244

OCT 16 2003

GE Medical Systems
P.O. Box 414, W-400
Milwaukee, WI 53201 USA

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

Identification of Submitter: Larry A. Kroger, Ph.D.
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GE Medical Systems
Tel. (262) 544-3894
Summary prepared: 5 September 2003

Identification of Product: Digital Fluoroscopic Imaging System
Classification Name: Fluoroscopic X-ray system – 21 CFR 892.1650
Manufacturer: GE Medical Systems Europe
283, rue de la Minière
78530 Buc Cedex, France
Distributed by: GE Medical Systems, Milwaukee, WI

Marketed Devices: The GE Medical System's Innova 4100, with a new Tilt table option for patient positioning, for diagnostic fluoroscopic imaging is substantially equivalent to *Siemens Axiom Artis (K021021).* This opinion is based on the information contained in the comparison table (Attachment 3), and the product data sheets (Attachment 4 & 5).

Device Description: The new tilt table is offered as an option for Innova 4100, in place of the existing Omega V table, which is part of the Innova 4100 system already cleared under K023178.

Materials: All construction and materials are compliant with UL 2601 and IEC 60601-1.

Design: There are hardware and software redundancies to prevent from single point failures that could cause unintended motion.

Energy Source: 480 VAC 50/60Hz.

Indications for Use: The Digital Fluoroscopic Imaging System with tilt table option is indicated for use in generating fluoroscopic images of human anatomy for diagnostic and intervention angiography procedures in both normal and tilted condition of patient. This

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

GE Medical Systems
% Mr. Donald James Sherratt
Medical Stream Director
Intertek Testing Services
70 Codman Hill Road
BOXBOROUGH MA 01719

JUL 30 2012

Re: K033244
Trade/Device Name: Model Innova 4100 with Tilt Table Option
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB and JAA
Dated: October 6, 2003
Received: October 7, 2003

Dear Mr. Sherratt:

This letter corrects our substantially equivalent letter of October 16, 2003.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INTENDED USE

510(k) Number (if known): K033264

Device Name: **Digital Fluoroscopic Imaging System – Innova 4100 with optional Tilt Table**

Indications for Use

The **Digital Fluoroscopic Imaging System** is indicated for use in diagnostic and interventional angiographic procedures of human anatomy. It is intended to replace image intensifier fluoroscopic systems in all diagnostic or interventionnal procedures. This device is not intended for mammography applications.

The new tilt table will support performing procedures like CO_2 studies, Venography.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

✓

Prescription Use _____ OR Over-The-Counter Use_____
(Per 21 CFR 801-109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033264